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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,928	04/26/2001	Philippa Marrack	2879-76	2069

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SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/844,928	Marrack et al.
Examiner	**Art Unit**
G.R. Ewoldt, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 28, 2002*

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-51* are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2, 4, 5, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 424, subclass 278.1 and Class 530, subclass 388.22.

II. Claims 1-3, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 424, subclass 351 and Class 530, subclasses 351 and 388.22.

III. Claims 1, 6, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 424, subclass 278.1 and Class 530, subclass 388.22 and 388.23.

IV. Claims 1, 7, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 435, subclass 91.1 and Class 530, subclass 388.22.

V. Claims 1, 8, 9, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an agent that binds to IL-2 and blocks or prevents interaction of IL-2 with an IL-2 receptor, classified in Class 435, subclass 91.1 and Class 530, subclass 388.23.

IV. Claims 1, 2, 4, 5, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an agent that binds to and degrades IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.22.

VII. Claims 1-3, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an agent that binds to and degrades IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclasses 351.

VIII. Claims 1, 6, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an agent that binds to and degrades IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.23.

IX. Claims 1, 7, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an agent that binds to and degrades IL-2, classified in Class 435, subclass 91.1.

X. Claims 1, 8, 10, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an agent that binds to and degrades IL-2, classified in Class 435, subclass 91.1 and Class 436, subclass 24.5.

XI. Claims 1, 2, 4, 5, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.22.

XII. Claims 1-3, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclasses 351.

XIII. Claims 1, 6, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 530, subclass 388.23.

XIV. Claims 1, 7, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 435, subclass 91.1.

XV. Claims 1, 8, 11, 12, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an agent that blocks or decreases IL-2 receptor activity, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XVI. Claims 1, 2, 4, 5, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to an IL-15 receptor, including an antibody, and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XVII. Claims 1-3, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising IL-15 or an IL-15 homologue, and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XVIII. Claims 1, 6, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to IL-15 and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XIX. Claims 1, 7, 13, and 14-17, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising a nucleic acid encoding IL-15 or an IL-15 homologue, and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclasses 23.5 and 24.5.

XX. Claims 1, 8, 13, and 14-17,, drawn to a vaccine adjuvant and a vaccine, said adjuvant comprising an agent that binds to a regulatory region of a gene encoding IL-15 and an antisense nucleic acid that hybridizes to a gene encoding IL-2, classified in Class 424, subclasses 184.1 and 278.1 and Class 436, subclass 24.5.

XXI. Claims 18-33, drawn to a method to increase T lymphocyte memory, classified in Class 424, subclasses 184.1 and 278.1.

XXII. Claims 34-50, drawn to a method to reduce an autoimmune response, classified in Class 424, subclasses 184.1 and 278.1.

XXIII. Claim 51, drawn to a composition for decreasing an undesirable T cell response, classified in Class 424, subclasses 184.1 and 278.1.

2. Inventions I-XX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in *in vitro* assays.

3. Inventions I-XX are different products. They are distinct because their structures and/or modes of action are different. Whereas the products of Groups I, VI, XI, and XVI comprise binding agents, generally proteins such as antibodies, the products of Groups IV, IX, XIV, and XIX comprise nucleic acids encoding proteins. Nucleic acids and proteins are physically and functionally distinct chemical entities, as are polypeptides and the binding proteins which bind them. Note that Groups XVI-XX comprise antisense DNA which comprise yet another patentably distinct invention. Thus, each of the combinations of inventions set forth in Groups I-XX above comprises a patentably distinct invention.

4. Inventions XXIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in *in vitro* assays.

5. Inventions XXI and XXII are unrelated methods. Whereas the method of Group XXI would increase an immune response, the method of Group XII would reduce said response.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
June 30, 2003